Supreme Court, U.S.
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No.

In The

Supreme Court of the United States

John Doe/11 and Jane Doe/11,
parents of the deceased minor,
Monica Doe,

Petitioners,

v.

Secretary of the Department
of Health and Human Services

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. Did Congress intend the burden shifting that the United States Court of Appeals for the Federal Circuit imposed in the Decision below? *Doe/11 v. Secretary of HHS*, 601 F.3d 1349 (Fed. Cir. 2010).

II. What burden of proof did Congress impose upon petitioners who attempt to access the National Vaccine Injury Compensation Program who have suffered non-"table" injuries?

LIST OF PARTIES

John Doe/11 and Jane Doe/11 as representatives of the Estate of Child Doe/11, deceased, Petitioners.

United States, Respondent.

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PETITION FOR A WRIT OF CERTIORARI

John Doe/11 and Jane Doe/11, parents of the deceased minor, Monica Doe, respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

There are five decisions below. The opinion of the United States Court of Appeals for the Federal Circuit is reported as *Doe/11 v. Secretary of HHS*, 601 F.3d 1349 (Fed. Cir. 2010). There are two decisions from the United States Court of Federal Claims: *Doe/11 v. Secretary of HHS*, 87 Fed. Cl. 1 (Fed. Cl. 2009) and *Doe/11 v. Secretary of HHS*, 83 Fed. Cl. 157 (Fed. Cl. 2008). There are two special master decisions: *Doe/11 v. Secretary of HHS*, No. 99-212V, 2008 WL 4899356 (Fed. Cl. Spec. Mstr. Oct. 29, 2008) and *Doe/11 v. Secretary of HHS*, No. 99-212V, 2008 WL 649065 (Fed. Cl. Spec. Mstr. Jan 31, 2008).

JURISDICTION

The United States Court of Appeals for the

Federal Circuit denied petitioners' appeal on April 13, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

This case involves the interpretation of the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to -34.

STATEMENT OF THE CASE

This case arises out of the National Vaccine Injury Compensation Program. (42 U.S.C. §§ 300aa-10 to - 34.) In this Program, petitions are filed in the United States Court of Federal Claims, naming the Secretary of the Department of Health and Human Services as the respondent.

Petitions are initially heard by "special masters." *See* 42 U.S.C. § 300aa-12(d). Appeals are then heard by a judge at the United States Court of Federal Claims. *See* 42 U.S.C. § 300aa-12(e). Appeals may then be taken to the United States Court of Appeals for the Federal Circuit. *See* 42 U.S.C. § 300aa-12(f).

42 U.S.C. § 300aa-11(b)(1)(A) provides that

"any person who has sustained a vaccine-related injury" or "the legal representative of any person who died as the result of the administration of a vaccine" may file a petition for compensation under the Program. A petitioner in the Vaccine Program may establish their vaccine injury by two distinct routes. A petitioner may proceed under a "table" theory, *see* 42 U.S.C. § 300aa-11(c)(1)(C)(i); or under a non-"table" theory by proving causation, *see* 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). (The vaccine injury table is set forth in 42 U.S.C. § 300aa-14.) In the instant case, petitioners proceeded under a non-"table" theory.

When establishing a vaccine injury, subsection 13(a)(1)(A) of the statute requires petitioner to prove by preponderant evidence the matters required in subsection 11(c)(1). However, if an alternative cause (termed "factors unrelated") is alleged, subsection 13(a)(1)(B) places the burden on respondent, the government, to present such proof. In relation to these subsections, and the parties respective burdens, the United States Court of Appeals for the Federal Circuit (Federal Circuit) has held that subsection 13(a)(1)(B) places the burden on respondent to establish a "factors unrelated" defense.

> Moreover, it would be unusual to require a party to prove that "there is not a preponderance of the evidence," as our legal system rarely requires a party to prove a negative. A plain reading of the statutory text more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence.

Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007).

The Federal Circuit, in *Walther*, then held:

> We conclude that the petitioner does not bear the burden of eliminating alternative independent potential causes, and, to the extent the special master assigned that burden to the claimant, we conclude that he erred.

Id. at 1152.

If the government wishes to attempt to establish an alternative cause, Congress expressly prohibited the government from using

"idiopathic, unexplained, unknown, hypothetical, or undocumentable" causes. 42 U.S.C. § 300aa-13(a)(2)(A).

John Doe/11 and Jane Doe/11 filed a petition for vaccine compensation on April 8, 1999. Petitioners claimed that their daughter, Monica, died at the age of seven weeks, on December 21, 1994, as the result of a hepatitis B vaccination she received earlier that day. Petitioners claimed that the hepatitis B vaccination caused an aberrant immune response which caused her death. The government defended by alleging that Monica died of "SIDS" (Sudden Infant Death Syndrom). As the court below recognized, "SIDS" is, by definition, idiopathic.

A hearing was held on their petition on October 12, 2006, in Eugene, Oregon. The special master issued her first decision denying compensation on January 31, 2008. Doe/11 *v. Secretary of HHS*, No. 99-212V, 2008 WL 649065 (Fed. Cl. Spec. Mstr. Jan 31, 2008). An appeal was taken by petitioners on March 1, 2008. The United States Court of Federal Claims issued its Opinion and Order on July 31, 2008, vacating the special master's decision and remanding for

further proceedings. Doe/11 *v. Secretary of HHS*, 83 Fed. Cl. 157 (Fed. Cl. 2008). The special master issued her second Decision on October 29, 2008, wherein she again denied compensation. Doe/11 *v. Secretary of HHS*, No. 99-212V, 2008 WL 4899356 (Fed. Cl. Spec. Mstr. Oct. 29, 2008). An appeal was again taken by petitioners on December 1, 2008. The United States Court of Federal Claims issued its Opinion and Order on April 22, 2009, affirming the special master's decision. Doe/11 *v. Secretary of HHS*, 87 Fed. Cl. 1, 2009 WL 1315449 (Fed. Cl. 2009). An appeal was then taken by petitioners to the United States Court of Appeals for the Federal Circuit. In an opinion dated April 13, 2010, the Federal Circuit affirmed. *Doe/11 v. Secretary of HHS*, 601 F.3d 1349 (Fed. Cir. 2010).

The Federal Circuit held that the special master did not violate the prohibition from subsection 300aa-13(a)(2)(A) on idiopathic defenses petitioners were required to disprove SIDS in order to establish their *prima facie* case. The Court below held:

> [T]he special master did not commit legal error in considering evidence of

> SIDS, an allegedly alternative cause. Nothing in the Vaccine Act prohibits the government from presenting evidence that the petitioner's injury was due to "factors unrelated" to the vaccine (here, SIDS). Under 42 U.S.C. § 300aa-13(a) and *de Bazan*, [*DeBazan v. Sec'y of HHS*, 539 F.3d 1347 (Fed. Cir. 2008)] the special master could consider such evidence in deciding whether Doe established a prima facie case; the Vaccine Act only prohibits the government from *rebutting* an established prima facie case with an idiopathic condition like SIDS. 42 U.S.C. § 300aa-13(a)(2)(A).

Doe/11 v. Secretary of HHS, 601 F.3d 1349, 1351-52 (Fed. Cir. 2010) (emphasis in the original). App. A, 4a.

This appeal followed.

REASONS FOR GRANTING THE WRIT

This petition addresses the United States Court of Appeals for the Federal Circuit's interpretation of the National Vaccine Injury

Compensation Program, 42 U.S.C. § 300aa-10 to -34 (1986). In the Decision below, the Federal Circuit created a standard that impermissibly shifts the burden to petitioners to disprove "factors unrelated" defenses. This burden shifting is contrary to the plain language of the statue, specifically 42 U.S.C. § 300aa-13(a). This new burden shifting rule is also contrary to the earlier Federal Circuit precedent of *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146 (Fed. Cir. 2007). This burden shifting rule is also contrary to the prior pronouncement of this Court:

> While a claimant may establish prima facie entitlement to compensation by introducing proof of actual causation, § 300aa-11(c)(1)(C)(ii), she can reach the same result by meeting the requirements of what the Act calls the Vaccine Injury Table.... The Secretary of Health and Human Services may rebut a prima facie case by proving that the injury or death was in fact caused by "factors unrelated to the administration of the vaccine."

Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995).

The Decision below also effectively eliminates subsection 300aa-13(a)(2)(A), by which Congress intended to prohibit the use of "idiopathic, unexplained, unknown, hypothetical, or undocumentable" factors unrelated defenses.

The Decision below is also in error in attempting to define petitioners' initial burden in establishing their *prima facie* case. There is no well defined standard which establishes petitioners' burden in this Program. Therefore, results in this Program are wildly divergent.

Anyone who receives a vaccine covered by this Program (which includes virtually all regularly scheduled vaccines, including the flu vaccine and all childhood vaccines) in this country and suffers an injury is required to first access this Program before she can prosecute her private rights in our Article III courts. See 42 U.S.C. § 300aa-11(a)(2). Therefore, this Program impacts the rights of everyone in this country who receives vaccines or has their children vaccinated. There are presently over five thousand petitions pending in this Program. It was the intent of Congress that awards in this Program be made to "vaccine-injured persons quickly, easily, and with certainty and generosity." H.R.Rep. No. 99-908, at 3 (1986),

1986 U.S.C.C.A.N. at 6344. The Decision below will have the effect of thwarting meaningful access to this Program by vaccine injured people in this country.

This Court needs to grant this writ of certiorari and define the parties' burdens in this Program.

I.

Did Congress intend the burden shifting that the United States Court of Appeals for the Federal Circuit imposed in the Decision below? *Doe/11 v. Secretary of HHS*, 601 F.3d 1349 (Fed. Cir. 2010).

In proceedings in the Vaccine Program, petitioners present their case in accordance with 42 U.S.C. § 300aa-13(a)(1)(A). If respondent wishes to allege a cause, other than the vaccine, respondent bears the burden of proof in accordance with 42 U.S.C. § 300aa-13(a)(1)(B). "These are two separate inquiries, with each party responsible to carry their burden of proof." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1149-1150 (Fed. Cir. 1992). In *Walther v. Sec'y of Health & Human Servs.*, the Federal Circuit also provided guidance on the

issue of the parties' respective burdens by applying the Restatement (Second) of Torts.

> Thus, applying the Restatement to the Vaccine Act context, the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm.

485 F.3d 1146, 1151 (Fed. Cir. 2007).

Moreover, Congress expressly prohibited respondent from using "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" when presenting a "factors unrelated" defense. 42 U.S.C. § 300aa-13(a)(2)(A). SIDS by definition is an unexplained death and is, therefore, prohibited as a defense in this Program. The court below did not take issue with the fact that SIDS was an idiopathic defense. Instead, to get around subsection 300aa-13(a)(2)(A)'s prohibition on idiopathic defenses, the Federal Circuit simply shifted the burden to petitioners to disprove SIDS. The court below held:

> [T]he special master could consider such evidence in deciding whether Doe established a prima facie case; the Vaccine Act only prohibits the government from *rebutting* an established prima facie case with an idiopathic condition like SIDS. 42 U.S.C. § 300aa-13(a)(2)(A).

Doe/11, 601 F.3d at 1351-52. App. A, 4a.

It is, of course, true that Congress never expressly prohibited the use of idiopathic alternate causes as part of petitioners' case-in-chief. However, that is because Congress assigned respondent, not petitioners, with the burden of proving alternate causes. Congress did not assign petitioners with the task of proving the negative.

The court below cited its earlier holding in *De Bazan v. Sec'y of HHS*, 539 F.3d 1347 (Fed. Cir. 2008) for support. See *Doe/11*, 601 F.3d at 1351. App. A, 3-4a. The court's reliance on *De Bazan* was misplaced. *De Bazan* did not involve allegations of an alternate cause. The Federal Circuit in *De Bazan* simply held that evidence in a case that deals with petitioners' *prima facie* case, whether

sponsored by petitioners or respondent, can and should be dealt with as part of petitioner's *prima facie* case.

> The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.

Id. at 1353. The court in *De Bazan* then observed that the government did not allege a "factors unrelated" defense.

> Here, the government's evidence did not concern any factors unrelated to the vaccine.

Id. at 1354.

In fact, the Federal Circuit's decision in *De Bazan* supports petitioners' interpretation of the statute as requiring the government to carry its burden in relation to "factors unrelated" defenses.

> Further, the petitioner's case-in-chief concerns the medical evidence relating to the possible role the *vaccine* had in causing her injury. The government's burden, in contrast, concerns "factors unrelated to the administration of the vaccine described in the petition." *See* 42 U.S.C. § 300aa-13(a)(1)(B).

Id. at 1353-54. (emphasis in the original). The court in *De Bazan* then held that it is the government's burden to establish "factors unrelated" defenses.

> The government then must provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury.

Id. at 1354. *De Bazan* provides no support for the impermissible burden shifting that has occurred in this case.

The burden shifting imposed by the court below is also error because it would effectively write the "factors unrelated" subsection of this

Program out of the statute. The Federal Circuit also addressed this issue in its *Walther* decision.

> Indeed, placing the alternative causation burden on the petitioner would essentially write § 300aa-13(a)(1)(B) out of the statute. On the one hand, if the petitioner did not successfully eliminate other causes, then the petition would fail and the second prong would not be reached. On the other hand, if the petitioner did eliminate alternative causes, the second prong would not be reached because the question of alternative causation would already have been resolved. Thus, construing the statute in such a way would make 300aa-13(a)(1)(B) redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative."

Walther , 485 F.3d at1150 (citing Colautti v. Franklin, 439 U.S. 379, 392 (1979).

The decision in this case is a perfect example of this problem. If the "factors unrelated" defense of SIDS is analyzed as part of petitioners' case, as was done in this case, then when was respondent going to be required to demonstrate, by preponderant evidence, that this SIDS defense was the actual cause of death (which is an oxymoron) or that this idiopathic defense was a legally cognizable defense in this Program? The government was not required to meet its burden in either respect. Instead, the burden was shifted to petitioners to prove a negative. (In this case, an idiopathic negative.)

The court below also made reference to *dicta* from its earlier holding in *Walther* for support. *See Doe/11*, 601 F.3d at 1358. The court's reliance on *Walther* is also misplaced. The Federal Circuit in *Walther* made the following observation (which is clearly *dicta).*

> On the other hand, a petitioner is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a prima facie case, as was true in *Pafford.*

> [*Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1359 (Fed. Cir. 2006)] In such instances, clearly the special master must evaluate what evidence a claimant presents as part of determining whether the claimant makes a prima facie case.

Walther, 485 F.3d at 1151.

As a practical matter a petitioner will, in most cases, attack the government's "factors unrelated" defenses. The petitioner does not know in advance what is going to impress the special master and a petitioner only gets "one bite" at proving causation. However, this reality does not change the statutory framework of this program, which imposes on respondent the burden of proving "factors unrelated." Also, clearly, this *dicta* from *Walther* does not even address the proposition that the court may get around this Program's prohibition on the use of idiopathic defenses by shifting to petitioners the burden of disproving a defense raised by the government.

II.

What burden of proof did Congress impose upon petitioners who attempt to access the National Vaccine Injury Compensation Program who have suffered non-"table" injuries?

The Vaccine Act provides for the establishment of causation by two distinct routes. Petitioner may proceed under a "table" theory, *see* 42 U.S.C. § 300aa-11(c)(1)(C)(i), or under a non-"table" theory by proving causation, *see* 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). In the instant case, petitioners have proceeded under a non- "table" theory.

Petitioners ask this Court to define petitioners' burden in proving their *prima facie* non-"table" case. At present, the precedent from the United States Court of Appeals for the Federal Circuit varies on this issue and the test applied in this case is simply unworkable.

In non-"table" cases, the statute simply states that petitioners are to show that they sustained an injury "which was caused by a [covered] vaccine." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Subsection 13 then instructs that

petitioners must make this showing by "a preponderance of the evidence." 42 U.S.C. § 300aa-13(a)(1)(A). The *"Althen"* test, which was applied in this case, was a creation of the United States Court of Appeals for the Federal Circuit. In the instant case, the Federal Circuit explained petitioners' burden by citing its earlier decision in *Althen v. Sec'y of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

> [A] claimant must prove three things: (1) a medical theory causally connecting the vaccination to the injury, (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury, and (3) a proximate temporal relationship between the vaccination and the injury.

Doe/11, 601 F.3d at 1351. App. A, 2a.

The Federal Circuit has also explained petitioners' burden by relying on the Restatement (Second) of Torts. In *Shyface v. Sec'y of HHS*, 165 F.3d 1344 (Fed. Cir. 1999), the Federal Circuit held:

> We adopt the Restatement rule for purposes of determining vaccine injury, that an action is the "legal cause" of harm if that action is a "substantial factor" in bringing about the harm, and that the harm would not have occurred but for the action.

Id. at 1352. In the instant case the Federal Circuit did not analyze petitioners' proof using the *Shyface* test.

The *Althen* test, which was applied in this case, is internally inconsistent, illogical and unworkable. There are three steps under *Althen*: (1) a medical theory causally connecting the vaccination to the injury, (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury, and (3) a proximate temporal relationship between the vaccination and the injury. Step one from *Althen* is straight forward. It asks if petitioners can present a medical theory of how the vaccine could produce the injury complained of. Step three from *Althen* is also straight forward. It asks if the injury occurred in a medically appropriate time frame. However, step two then asks the ultimate question that necessarily encompasses both steps one and three.

For example, if a vaccine could only cause seizures within the first 72 hours after a vaccination, but the child's seizures started 14 days after the vaccination, one could not say that there was a logical sequence of events that pointed to the vaccine as the cause of the injury. The same is true in relation to step one from the *Althen* test. If the vaccine could not cause the injury complained of, then there certainly could not be a logical sequence of events that would point to the vaccine. Step two simply cannot logically co-exist with steps one and three. Attempting to assign some independent meaning to step two of the *Althen* test has resulted in confusion.

Two cases illustrate the confusion, and divergent results, from attempting to apply the three step *Althen* test, *Andreu v. Secretary of DHHS,* 569 F. 3d 1367 (Fed. Cir. 2009) and *Moberly v. Sec'y of HHS*, 592 F.3d 1315 (Fed. Cir. 2010).

Petitioners in *Andrue* prevailed. However, the following excerpt illustrates the court's confusion in attempting to assign some meaning to step two of the *Althen* test. In attempting to apply step two, the Federal Circuit in *Andrue* relied on

the opinion and reasoning of the treating neurologist, Dr. Deray.

> First, although he was able to identify a cause for seizures in 70 to 75 percent of his patients, Deray had found no cause-other than the DPT vaccination-to explain the seizures that Enrique experienced. . . . . Second, Enrique's history was "consistent with [the] DPT immunization causing seizures, in the sense that it occurred within three days of the shot."

Id. at 1376. (Internal citations omitted.)

As discussed above in Section I, it is not petitioners' burden to eliminate other causes, termed "factors unrelated," in establishing their *prima facie* case. Therefore, if *Althen* step two contemplates assigning this burden to petitioners, it violates the express terms of the statute. Also, the second reason the court gave for relying on Dr. Deray's opinion to establish step two of the *Althen* test was the time interval between the vaccination and the seizures, which is redundant with step three of the *Althen* test. The Federal Circuit's

decision in *Andreu* provides no clarity on how to apply step two from *Althen*.

Petitioners did not prevail in *Moberly*. The Federal Circuit in *Moberly* also attempted to apply the *Althen* test. *See Moberly*, 592 F.3d 1322 -23. The court in *Moberly* described the evidence as follows:

> Molly was healthy before she received her second DPT vaccination; she suffered seizures within 36 hours of receiving the vaccine; DPT vaccine is capable of causing seizures and permanent brain damage; and no alternative cause of her condition has been identified. As the special master noted, the problem with that evidence is that it amounts at most to a showing of temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury.

Id. at 1323.

The court held that the vaccination that Molly Moberly received could cause the injuries complained of, seizures. Which satisfies *Althen* step one. The court also found that the injury occurred within the appropriate time frame. Which satisfies *Althen* step three. The court also found that Molly Moberly did in fact suffer the injury alleged, seizures. The court further found that there was no alternate cause for her seizures. However, the court held that petitioners' failed to satisfy their burden and dismissed their petition. In describing the inadequacies of petitioners' case the court went on to use the phrase "without more." *Id.* What "more" is needed in this Program, however, is left unanswered.

The confusion in this Program in relation to petitioners' burden stems from the three part test from *Althen*. Specifically, step two from *Althen* does not logically co-exist with steps one and three. The language from the *Althen* step two test, "a logical sequence of cause and effect," was first used in this Program in *Grant v. Sec'y of HHS., 956 F.2d 1144, 1148 (Fed. Cir. 1992).* However, steps one and three from *Althen* do not exist in *Grant*. Steps one and three were created by the Federal Circuit in *Althen*. This language from *Grant*, and step two from *Althen*, finds its origins in the Alabama Supreme Court decision *Southern*

R. Co. v. Dickson, 100 So. 665, 669 (Ala. 1924) (a RR personal injury/negligence case). The court held:

> There may be two or more plausible explanations as to how an event happened or what produced it; yet, if the evidence is without selective application to any one of them, they remain conjectures only. On the other hand, if there is evidence which points to any one theory of causation, indicating a logical sequence of cause and effect, then there is a juridical basis for such a determination, notwithstanding the existence of other plausible theories with or without support in the evidence.

Id. at 669 (emphasis added).

Steps one and three from the *Althen* test are not found in *Dickson* or its progeny. Those additional / redundant steps were added by the Federal Circuit in *Althen*.

A modified *Althen* three part test would be workable. Step one should remain the same, a

petitioner, logically, needs to provide the court with a theory of how the vaccine could cause the injury complained of. Step two should be clarified to require only that petitioners are required to prove that the child in fact suffered the injury or condition complained of. And step three should remain the same, petitioners need to establish the appropriate time frame for the injury or condition to develop.

If petitioners establish that 1) their healthy child received a vaccine that can cause an injury, 2) that their child actually suffered that injury, 3) within an established time frame, and the government can provide no better explanation for how the child was injured, **then that child should be compensated** in this **compensation Program**. That is, after all, why Congress created this Program.

The three step *Althen* test, which was applied in this case, leaves special masters and practitioners in this Program groping to assign some meaning to step two from *Althen*. The results have been unworkable. This Court needs to define the parties burdens under this statute.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2009-5096

JOHN DOE, 11, and JANE DOE, 11,
As Representative of the Estate of
CHILD DOE, 11, Deceased,
Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

Filed April 13, 2010

Before BRYSON, GAJARSA, and PROST, Circuit Judges.
PROST, Circuit Judge.

This is a Vaccine Act [FN1] case. We must decide whether the claimants, John and Jane Doe

(collectively "Doe"), met their burden of proving that their daughter Monica's death was caused by a hepatitis B vaccination. See 42 U.S.C. § 300aa-11. It is an off- Table case because Monica's injury is not listed in the Vaccine Act Injury Table. See 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3(a). Accordingly, the burden was on Doe to prove that Monica's death was actually caused by the vaccine. 42 U.S.C. § 300aa-11(c); see Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007).

Under the test for causation set out in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005), a claimant must prove three things: (1) a medical theory causally connecting the vaccination to the injury, (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury, and (3) a proximate temporal relationship between the vaccination and the injury. Id. at 1278. In this case, the special master denied compensation, concluding that Doe failed to prove prongs two and three of the Althen test by a preponderance of evidence. In a

careful, well-reasoned opinion, the U.S. Court of Federal Claims upheld the special master's decision. Doe ex. rel Estate of Child Doe v. Sec'y of Health & Human Servs., 87 Fed. Cl. 1 (2009) ("Doe IV"). We now affirm.

Our review primarily focuses on the special master's factual findings, which were subsequently adopted by the Court of Federal Claims. Under the Vaccine Act, the question is whether these findings were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. 42 U.S.C. § 300aa-12(e)(2)(B). In addition, we must decide whether the special master committed legal error by considering evidence of a possible alternative cause, Sudden Infant Death Syndrome ("SIDS"), in deciding whether Doe established a prima facie case.

We reach the same conclusion as the Court of Federal Claims. The special master's factual findings regarding the significance of the decedent's length, weight of her brain and other organs, and pre-death behavior were not arbitrary or capricious, particularly in light of the credibility findings made as to the parties' respective experts. Further, under this court's decisions in de Bazan

v. Secretary of Health and Human Services, 539 F.3d 1347 (Fed. Cir. 2008), and Pafford v. Secretary of Health and Human Services, 451 F.3d 1352, 1359 (Fed. Cir. 2006), the special master did not commit legal error in considering evidence of SIDS, an allegedly alternative cause. Nothing in the Vaccine Act prohibits the
government from presenting evidence that the petitioner's injury was due to "factors unrelated" to the vaccine (here, SIDS). Under 42 U.S.C. § 300aa-13(a) and de Bazan, the special master could consider such evidence in deciding whether Doe established a prima facie case; the Vaccine Act only prohibits the government from rebutting an established prima facie case with an idiopathic condition like SIDS. 42 U.S.C. § 300aa-13(a)(2)(A).

BACKGROUND

Monica Doe was born in October 1994. On the day she was born, she received her first hepatitis B vaccination. Monica was discharged from the hospital the next day.

At approximately 2 p.m. on December 21, 1994, Monica received her second vaccination for

hepatitis B. At the time, Monica was seven and a half weeks old and weighed eleven pounds. The vaccine was administered to Monica's thigh. After the doctor's appointment, the family went shopping. During the shopping trip, Monica was carried in an infant car seat by her father. Her father testified that Monica slept the entire time, without evidencing a fever, abnormal jerking, or crying. Her mother testified that Monica was awake during the shopping trip and unusually quiet, since Monica "usually" cried. To the extent their accounts conflicted, the special master credited the father's testimony that Monica was asleep, because the father was the one carrying Monica.

Around 5 p.m., the family returned home. Monica's mother and two brothers lay down for a nap in the bedroom, while Monica and her father remained in the living room. Monica's father lay down on the couch to watch the news, positioning Monica next to him, propped face up on a pillow. Monica's father testified that he fell asleep on the couch between 5:30 and 6 p.m. When he awoke approximately thirty minutes later, Monica was "blue in the face." Awakened by calls from her husband, Monica's mother observed Monica lying

face up on the pillow, with a "bluish" complexion. Monica was not breathing when her parents called 911 at 6:49 p.m. The ambulance arrived about five minutes later, by which time Monica's father had begun CPR.

The emergency medical technician ("EMT") who responded to the 911 call observed Monica face up on the couch, receiving CPR from a fire department emergency responder. The EMT found Monica had no heartbeat and was not breathing, though her skin was warm and dry. He observed that Monica's extremities were "mottled and chest and abdomen were white," while her abdomen was "distended." At the emergency room, a physician diagnosed Monica as having suffered cardiopulmonary arrest, cause unknown. Monica was pronounced dead at 8 p.m., approximately six hours after she received her hepatitis B vaccination.

A forensic pathologist named Dr. Robert Anthony performed an autopsy the following day. His report notes a "moderate amount of fixed purple livor mortis over the posterior aspects of the body surfaces." Monica's stomach and bladder were empty. Her lungs, however, exhibited "moderate

pulmonary congestion and edema," and her heart had "rare epicardial petechiae." Significantly, Dr. Anthony opined that Monica's brain was "grossly unremarkable," with "no evidence of edema or herniation" and "clear, glistening and intact" meninges. The report lists a brain weight of 570 grams and SIDS as the cause of death. At the time he performed the autopsy, Dr. Anthony did not know the circumstances surrounding Monica's death.

Monica's parents (collectively, "Doe") subsequently filed a claim under the Vaccine Act on behalf of Monica's estate. The claim alleges that Monica died as a result of receiving a hepatitis B vaccination on December 21, 1994. The special master assigned to the case held an evidentiary hearing. Among the evidence presented at the hearing was expert testimony by Dr. John Shane and Dr. Alan Levin for Doe, and expert testimony by Dr. Enid Gilbert-Bamess and Dr. Christine McCusker for the government.

Dr. Shane, accepted as an expert in pathology generally, though not pediatric pathology, opined that Monica died from acute encephalopathy caused by the hepatitis B vaccine. In support of this

theory, Dr. Shane cited Monica's brain weight, which he testified was "abnormally" high for a child of that age and thus evidence of cerebral edema. Doe's other expert, Dr. Levin, similarly opined that Monica's death was caused by the hepatitis B vaccine. Accepted as an expert in immunology, Dr. Levin testified that the vaccine led to excessive cytokine release, followed by cerebral edema. The edema, in turn, resulted in decreased blood flow, causing Monica's death.

Both of the government's experts rejected Doe's theory of causation. Dr. GilbertBamess, qualified as an expert in pediatric neuropathology, opined that the hepatitis B vaccine was not the cause of Monica's death. She rejected Dr. Shane's conclusion that Monica's brain weight was abnormally high, finding no evidence of significant brain edema or other abnormalities in the same slides reviewed by Dr. Shane. Nor did Dr. Gilbert-Bamess agree with Dr. Shane's diagnosis of acute encephalopathy, because "one would expect to see considerable brain edema" and "very likely" herniation of the brainstem as the cause of death, neither of which were found here.

The government's other expert, Dr. McCusker, similarly disagreed with Doe's experts. Dr. McCusker was accepted as an expert in pediatric immunology. Dr. McCusker opined that the timing of Monica's death undermined Dr. Levin's cytokine storm theory, because edema resulting from such inflammation would have required days, not hours, to develop. Dr. McCusker elaborated that Monica exhibited no symptoms characteristic of an escalating cytokine response or edema, such as fever, seizures, vomiting, high-pitched screaming, marked somnolence, or coma.

The special master concluded that Doe did not establish a prima facie case that the hepatitis B vaccination caused Monica's death. Instead, the special master found that Monica's death was caused by SIDS, a factor unrelated to the vaccination.

The Court of Federal Claims reversed. Doe ex rel. Estate of Doe v. Sec'y of Dep't of Health & Human Servs., 83 Fed. Cl. 157, 158 (2008) ("Doe II"). It held that the special master improperly shifted the burden of proof to Doe by requiring that Doe affirmatively disprove SIDS caused

Monica's death as part of their prima facie case. Id. The court remanded the case to the special master with instructions to reweigh the evidence in light of the burden of proof set forth in Althen and Walther. Doe II, 83 Fed. Cl. at 176.

On remand, the special master again concluded that Doe was not entitled to compensation because Doe had not established a prima facie case of causation. Specifically, the special master found that Doe had failed to prove the second or third prong of Althen by a preponderance of evidence. The special master still considered evidence relating to SIDS, but only in evaluating whether Doe's proposed sequence of cause and effect was plausible. Doe again petitioned for review.

The Court of Federal Claims denied Doe's petition. Doe IV, 87 Fed. Cl. at 15. In upholding the special master's decision, the court found the special master's factual findings were not arbitrary and capricious, including those with respect to Monica's brain weight. Id. at 12. The court also held that the special master did not err in considering evidence of SIDS in deciding whether Doe established a prima facie case. Id. at 13-14.

Doe now appeals. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

We review de novo decisions by the Court of Federal Claims arising under the Vaccine Act. Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). In doing so, we apply the same standard the Court of Federal Claims applied to the special master's decision: Factual findings are reviewed under the arbitrary and capricious standard; legal rulings are reviewed for whether they are in accord with the law. Id.; see also 42 U.S.C. § 300aa-12(e)(2)(B).

I. Special Master's Fact Finding

We begin with certain factual findings made by the special master. These findings matter because they were the basis on which the special master rejected Dr. Shane's theory of cause and effect, which posited that Monica died as the result of cerebral edema caused by acute encephalopathy. The primary evidence Dr. Shane cited in support of his theory was Monica's brain

weight of 570 grams, which he deemed "abnormally" high for a child of her age and so heavy it could only be explained by severe edema and encephalopathy. This opinion was based in part on Dr. Shane finding Monica's height to be in the fiftieth percentile for her age group and attributing the above-average weights of her other organs to edema. On appeal, Doe argues that the special master's findings of fact as to Monica's height, weight of her brain and other organs, and pre-death behavior were arbitrary and capricious. For the following reasons, we do not agree.

The special master concluded that Monica's brain was not abnormally heavy or significantly "edematous," as Dr. Shane claimed. In reaching this conclusion, the special master relied on expert testimony and on several different tables of average brain weights for infants. For a two-month old, the medical literature listed weights of 489 grams, 490 grams, and 516 grams. Dr. Shane testified that the expected range for brain weight was "440 to 540" grams, given the standard deviation for the table he used. Accounting for the table's listed error of 14 grams, Dr. Shane opined that 555 grams would be the "top limit of normal." Noting that Monica's brain weight was "not much beyond"

the range of normal brain weights, the special master declined to credit Dr. Shane's opinion that brain weight alone proved Monica suffered cerebral edema.

The special master also evaluated the significance of Monica's brain weight based on her height. In support of this assessment, the special master cited medical studies showing that brain weight depends on age and height. For this purpose, the special master estimated Monica's height to be 23 inches. In doing so, the special master credited the hospital's measurement of 21.75 inches taken at Monica's birth and the growth differential reflected on her pediatric growth chart. The resulting estimate was 2 inches shorter than the longest recorded length (25 inches) from Monica's autopsy, but longer than her pediatrician's measurements. The special master noted that the pediatrician could have been affected by the challenge of measuring a squirming child. Based on her estimate, the special master found Monica exceeded the average height for infants her age. In light of Monica's above-average height, the special master found Monica's brain weight was "not out of proportion with her body length and weight."

Finally, the special master considered whether Monica's post-vaccination behavior was consistent with the expected signs and symptoms of encephalopathy. Based on the testimony of government experts Dr. Gilbert-Bamess and Dr. McCusker, the special master concluded that Monica's observed sleepiness and disinterest in eating were not abnormal reactions. In support of this assessment, the special master noted that neither Monica's medical records nor any witness reported other symptoms of encephalopathy following the vaccination, such as irritability, fever, vomiting, or seizures. Though Dr. Shane opined that Monica's behavior was "abnormal," he admitted that a pediatrician, such as government expert Dr. McCusker, would be better qualified to render an opinion. Dr. McCusker testified that Monica's reactions were normal, without any of the clinically-recognized symptoms that precede severe somnolence indicative of encephalopathy.

Finally, the special master cited other evidence in discounting Dr. Shane's conclusion that Monica's brain was severely edematous. This evidence included Dr. Anthony's autopsy report, which found no edema except in the lungs. Dr. Anthony opined that Monica's brain was "grossly

unremarkable," with "no evidence of edema or herniation." Similarly, government expert Dr. Gilbert-Barness testified that she saw "very little abnormality" in the autopsy slides of Monica's brain and none of the changes Dr. Shane described or attributed to edema. Though Dr. Gilbert-Barness agreed that Monica had heavier than average organs, she disagreed as to the cause. According to Dr. Gilbert-Barness, their heaviness did not have to be explained by edema, as Dr. Shane suggested. Dr. Gilbert-Barness opined that organs could be heavy due to SIDS caused by asphyxiation, in which blood vessels dilate and organs become congested with blood.

Doe is correct that not all of the evidence in the record supports the special master's findings. That, however, is not the question. On appeal, we must determine whether the special master's findings of fact are supported by substantial evidence. See Whitecotton by Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1105 (Fed. Cir. 1996). As chronicled in the Court of Federal Claims' thorough opinion, the special master conducted a detailed review of the testimony, medical records, and medical literature. Thus, as an initial matter, we cannot say that the special

master failed to consider important aspects of the record. See 42 U.S.C. § 300aa-13(b)(1); Hodges v. Sec'y of Dep't of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (noting that the role of appellate review Is not to second guess the Special Master's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process").

As for the specific factual findings, it was not arbitrary or capricious for the special master to conclude that Monica's brain was not significantly "edematous." The best support for Doe's theory of causation, encephalopathy followed by cerebral edema, was offered by Dr. Shane. The special master, however, chose not to credit Dr. Shane's testimony, because she found it unsupported by the facts of this particular case. These facts included Dr. Anthony's autopsy report, which described Monica's brain as "grossly unremarkable" with "no evidence of edema," and the testimony of expert Dr. Gilbert-Bamess's, who
saw "very little abnormality" in the autopsy slides. Because of the special master's unique position to see the witnesses and hear their testimony, such credibility assessments are "virtually unreviewable on appeal." Lampe v. Sec'y of Dep't of Health &

Human Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000); see also 42 U.S.C. § 300aa-13(b)(1); Bradley v. Sec'y of Dep't of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993). We see no basis for disturbing the special master's credibility findings as to Dr. Shane, Dr. McCusker, or Dr. Gilbert-Bamess. [FN2]

We similarly conclude that the special master's decision to evaluate Monica's brain weight in light of her height was not arbitrary or capricious. This decision was supported by medical literature detailing a correlation between an infant's height and brain weight. Given the widely varying estimates of Monica's height, the special master did not err by choosing an estimate between the minimum and maximum heights recorded. We cannot say that the special master's careful weighing of this conflicting evidence was "so clearly wrong as to be arbitrary or capricious." Lampe, 219 F.3d at 1367.

Nor can we say that it was arbitrary or capricious for the special master to conclude that Monica's pre-death behavior and weight of her other organs failed to support Dr. Shane's

encephalopathy diagnosis. The special master's ultimate conclusion was supported by the testimony of Dr. Gilbert-Bamess and Dr. McCusker, who both opined that Monica did not display other characteristic symptoms of encephalopathy, such as vomiting, seizures, or fever. As Dr. Shane admitted, Dr. McCusker was better qualified to offer an opinion on whether Monica's sleepiness was a normal reaction to the vaccine or the type of somnolence symptomatic of encephalopathy. Dr. McCusker opined that Monica's pre-death behavior was normal. The special master credited this testimony, as well as the testimony of Monica's father, who observed no fever, vomiting, or seizures. It is not our role to reweigh the factual evidence or assess whether the special master correctly evaluated the evidence. Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d 863, 871 (Fed. Cir. 1992).

Accordingly, we hold that the special master's factual findings were not arbitrary or capricious.

II. Evidence of Alternative Causes

We must also decide whether it was legal error under 42 U.S.C. § 300aa13(a)(2)(A) for the

special master to consider evidence of alternative causes in evaluating whether a *prima facie* case has been established in this off-Table case. Specifically, Doe contends that the special master erred when discussing prong two of the Althen test by considering evidence that SIDS, not the hepatitis B vaccine, caused Monica's death.

In this case, both parties presented evidence about an alternative cause of death, sudden infant death as the result of asphyxiation. In his expert report and at the hearing, Dr. Shane opined that the circumstances surrounding Monica's death and pathological findings at the autopsy were "inconsistent with a SIDS death." Dr. Shane went on to explain why the extent of cerebral edema he observed in Monica's brain, absence of multi-organ findings, and lack of prior upper respiratory problems were inconsistent with a SIDS death.

The government offered the testimony of Dr. Gilbert-Bamess. She explained that many deaths attributed to SIDS are now thought "very likely related" to the infant's sleeping position or bedding, with "most" related to an asphyxial death. In Monica's case, Dr. Gilbert-Bamess

opined that the nap environment created a risk of SIDS caused by asphyxiation. She explained that the congestion of Monica's abdominal organs and over-distinction of the lungs' alveoli were consistent with asphyxiation.

The medical literature in evidence states that "classic" findings in SIDS cases include petechiae, pulmonary congestion and edema, heavy organs, and an empty urinary bladder. Further, many of the infants who die of SIDS are tall for their age and have brain weights exceeding the ninety-ninth percentile for their age group, without evidence of cerebral edema. The special master noted that Monica displayed many of these classic SIDS findings.

The special master considered this SIDS evidence, along with other testimony, medical records, and medical literature in evaluating whether Doe's medical theory reflected a "logical sequence of cause and effect," as required by prong two of the Althen test. While noting some of the government's evidence might also have been relevant to a claim of alternative causation (i.e., SIDS) had Doe proved their prima face case, the special master only considered evidence of SIDS

"for the limited purpose of evaluating carefully the reliability of the medical underpinnings of petitioners' proposed causal sequence for a vaccine injury." Id.

Doe urges us to find fault with the special master considering any evidence of SIDS, a possible alternative cause, in deciding whether Doe established a prima facie case. Doe argues that such consideration is prohibited by 42 U.S.C. § 300aa-13(a). Section 300aa-13(a) establishes the terms for awarding compensation. It provides that "on the record as a whole," the special master must find (1) the petitioner "has demonstrated by a preponderance of evidence the matters required in the petition by section 300aa-1 I (c)(1)," and (2) "there is not a preponderance of evidence that the .. . death described in the petition is due to a factor unrelated to the administration of the vaccine described in the petition." 42 U.S.C. § 300aa-13(a)(1) (emphasis added).

The first requirement, demonstrating "the matters required by [42 U.S.C. § 300aa-11(c)(1)]," is what this court refers to as the petitioner's prima facie case. See, e.g., Walther, 485 F.3d at 1149; see also de Bazan, 539 F.3d at

1351; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1357 (Fed. Cir. 2006). To make out a prima facie case, the petitioner must show that the person received a vaccine set forth in the Vaccine Injury Table and sustained an illness, disability, injury, or condition caused by that vaccine. 42 U.S.C. § 300aa-11(c)(1). The second inquiry under § 300aa-13(a)(1) is whether the injury or death was due to a "factor unrelated" to the vaccination. While the burden of proving a prima facie case is on the petitioner, the government has the burden of showing the injury or death was caused by a "factor unrelated." Id. § 300aa13(a)(1)(B); see also de Bazan, 539 F.3d at 1352-54; Walther, 485 F.3d at 1150.

As relevant here, subsection (2) of § 300aa-13(a) limits the definition of "factors unrelated" by excluding any "idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness or condition." In other words, alternative causes that are "idiopathic, unexplained, unknown, hypothetical or undocumentable" cannot overcome a petitioner's prima facie case. 42 U.S.C. § 300aa-13(a)(1), (2). Nor can the special master require the petitioner to

eliminate alternative causes as part of establishing its prima facie case.

These restrictions on the second inquiry under § 300aa-13(a), however, are not implicated in this case. They are not at issue because Doe never established a prima facie case, so the burden (and attendant restrictions on what "factors unrelated" the government could argue) never shifted. Doe IV, 87 Fed. Cl. at 12; see Pafford, 451 F.3d at 1357-59; cf. Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344 (Fed Cir. 1999).

Accordingly, the questions here are different. They are whether the government may present evidence of alternative causes, and what limits, if any, constrain the special master's consideration of such evidence in evaluating the petitioner's prima facie case. By its plain terms, § 300aa-13 does not prohibit the government from presenting evidence of alternative causes. Instead, "like any defendant, [the government] is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief." de Bazan, 539 F.3d at 1353.

As for what the special master may do, neither § 300aa-13 nor our cases limit what evidence the special master may consider in deciding whether a prima facie case has been established. See de Bazan, 539 F.3d at 1353; see also Walther, 485 F.3d at 1151. Indeed, § 300aa-13(a) requires the special master's findings to be based "on the record as a whole." Thus, in de Bazan the government could present, and the special master could consider, evidence that petitioner's symptoms occurred too early to have been caused by the vaccine when evaluating petitioner's prima facie case, even though that evidence undermined petitioner's theory of causation. Id.

In this case, the special master did not commit legal error by considering evidence that Monica's death could have been caused by SIDS. Part of the evidence Doe offered was Dr. Shane's expert testimony, which attempted to eliminate SIDS as a potential cause of death. Specifically, Dr. Shane opined that Monica's death and the pathological findings at her autopsy were "inconsistent with a SIDS death." As this court explained in Walther, when petitioners attempt to eliminate other possible causes to buttress their theory of causation, the special master should

evaluate such evidence in determining whether a prima facie case has been established. 485 F.3d at 1151; see also Pafford, 451 F.3d at 1359. Because Dr. Shane supported his theory of causation by discounting SIDS as a possible cause, Doe's prima facie case depended in part on whether the special master credited Dr. Shane's opinion on SIDS. Evidence of SIDS thus "bore directly on whether the medical evidence supported [a conclusion] that the vaccine could be the cause in fact"; the special master's consideration of this evidence was both warranted and proper. de Bazan, 539 F.3d at 1354.

Allowing the special master to consider evidence of SIDS did not improperly shift the burden to Doe to rule out alternative causes. Evidence of SIDS was just one factor among many that the special master relied on in concluding that "the facts of the case" did not support Doe's theory of causation, and thus failed to establish a prima facie case. See § 300aa-13(a)(1). A petitioner's failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternative cause. See de Bazan, 539 F.3d at 1353-54. The special master denied compensation

because she determined that Doe failed to establish a prima facie case of causation based on a review of Doe's proposed theory in light of all the evidence, not because Doe failed to eliminate SIDS as an alternative cause of Monica's death.

CONCLUSION

For the foregoing reasons, we hold that the special master's fact finding was not arbitrary or capricious. Further, the special master's evaluation of the SIDS evidence was not contrary to law, as set out in § 300aa-12(a)(2)(E) or de Bazan. The judgment of the Court of Federal Claims is affirmed. AFFIRMED.

FN1. The official title is the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), Pub. L. No. 99-660, tit. III, § 311, 100 Sat. 3756 (codified as amended in scattered sections of 42 U.S.C.).

FN2. Though both Dr. Gilbert-Bamess and the special master cited a table of brain weights based on children with moderate to severe brain edema, any error was harmless. See Hines v. Sec'y of Health & Human Servs., 940

F.2d 1518, 1526 (Fed. Cir. 1991). This table was not the only fact the special master relied on, or even the most important one, in declining to credit Dr. Shane's theory. To the contrary, the special master's decision was based on a number of factors, including the autopsy results, Monica's greater-than-average height, Dr. Gilbert-Bamess's review of the autopsy slides, and Dr. Shane's own testimony regarding the "top limit of normal."

APPENDIX B

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

No. 09-212V

JOHN DOE/11 and JANE DOE/11,
as representatives of the Estate of
CHILD DOE/11, Deceased,
Petitioners,

v.

SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES,
Respondent.

Filed Under Seal: April 22, 2009

OPINION AND ORDER[FN1]

WILLIAMS, Judge

This matter comes before the Court on Petitioners' Motion for Review of the Special Master's Decision on Remand, which denied Petitioners' claim that the Hepatitis B vaccine caused the death of their daughter, Monica.

In the original Decision on Entitlement, the Special Master ruled that Petitioners did not establish that the vaccine caused Monica's death, and instead found that a "factor unrelated" to the Hepatitis B vaccination, Sudden Infant Death Syndrome (SIDS), which the Special Master characterized as asphyxiation, overlay or wedging, caused her death. This Court vacated the original decision and remanded the petition, finding inter alia that the Special Master had improperly allocated and applied the burden of proof.

On remand, the Special Master found that Petitioners failed to establish a prima facie case that the Hepatitis B vaccination caused Monica's death and did not reach the issue of whether Defendant established that an unrelated factor caused her death. In the instant Motion for Review, Petitioners argue that the Special Master failed to follow this Court's instructions on remand, issued arbitrary and capricious findings of fact on Monica's brain weight,

and erroneously considered evidence of SIDS as a factor unrelated in analyzing Petitioners' prima facie case. Because Petitioners have not demonstrated that their asserted legal or factual errors warrant reversal or remand, this Court upholds the Special Master's Decision on Remand.

Background[FN2]

On December 21, 1994, Monica, a healthy infant of seven and one-half weeks of age, received her second Hepatitis B vaccination at approximately 2:00 p.m.[FN3] The vaccination was administered in Monica's thigh. After Monica's appointment, the family went holiday shopping at a mall for several hours. Monica's father carried her in a transportable car seat, and she slept during the entire shopping trip and did not cry or interact with her parents. Monica's mother tried to feed Monica a bottle on several occasions towards the end of the shopping trip, but Monica did not drink from the bottle. Monica's parents did not take her temperature. The family returned home between approximately 5:00 and 5:30 p.m. that evening and took a nap. Monica's father laid Monica on a futon next to him, face up and propped up on a pillow. He slept from approximately 5:30 until 6:00 p.m. beside Monica, and upon awakening, discovered

that Monica, who was still propped up on a pillow face up, was "blue in the face" and not breathing.

Monica's mother called paramedics at 6:49 p.m., and her father performed CPR until the paramedics arrived via ambulance at 6:54 p.m. The paramedics "found [Monica] supine on couch." Pet'rs' Ex. 4 at 2. The paramedics determined that Monica had no heartbeat, pulse, or respiration, and she did not respond to CPR. Id. The emergency room records listed Monica's diagnosis as "cardiopulmonary arrest, unknown participant." Pet'rs' Ex. 5 at 6. The paramedics also noted that Monica's "skin was warm, dry and extremities] were mottled and chest and abd[omen] was white . . . and [patient's] abd[omen] was distend[ed]." Pet'rs' Ex. 4 at 1. Shortly after her arrival at the emergency room, Monica was diagnosed as having suffered cardiopulmonary arrest of an unknown cause, and she was pronounced dead at 8:00 p.m.

Forensic pathologist Robert M. Anthony M.D/Ph.D. performed an autopsy on Monica on December 22, 1994, the day after her death.[FN4] Dr. Anthony recorded Monica's weight as 12 pounds 12 ounces and her length as 25 inches. Dr. Anthony noted that Monica's bladder and stomach were both empty and

that her lungs revealed "moderate pulmonary congestion and edema." Pet'rs' Ex. 6 at 4-5.{FN5} Dr. Anthony determined the condition of Monica's brain to be "grossly unremarkable" with "no evidence of edema or herniation." Id. at 5. The autopsy report did not indicate that any of Monica's visceral organs, other than her lungs, showed the presence of edema. Id. at 3-5. Dr. Anthony recorded the cause of Monica's death as SIDS.[FN6]

The Althen Factors

In Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), the Federal Circuit set forth a three-pronged test a petitioner must meet in order to establish causation under the Vaccine Act. Under Althen, a petitioner must prove by a preponderance of the evidence:

> (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278.

The Special Master's First Decision, Vacatur and Remand

In the original Decision on Entitlement, the Special Master ruled that Petitioners did not establish that the vaccine caused Monica's death, and instead found that a "factor unrelated" to the Hepatitis B vaccination, Sudden Infant Death Syndrome (SIDS) -- which the Special Master characterized as asphyxiation, overlay or wedging -- caused her death.

The Court vacated the Special Master's decision and remanded the matter, finding that the Special Master had misallocated the burden of proof and effectively required Petitioners to disprove that SIDS was the cause of death as part of their prima facie case. The Court further ruled that, to the extent the Special Master had concluded that an idiopathic condition either defeated Petitioners' prima facie case of causation or constituted an unrelated factor that caused Monica's death, the decision was contrary to the Vaccine Act's definition of a "factor unrelated" as a cause that "does not include any idiopathic, unexplained,

unknown, hypothetical or undocumentable cause, factor, injury, illness or condition . . . ." 42 U.S.C. § 300aa-13(a)(2) (emphasis added). The Court instructed the Special Master to clarify what unrelated factor caused Monica's death and to assess whether such factor was idiopathic.

The Court also held that the Special Master placed an overly onerous burden of proof on Petitioners under Althen's prong one by requiring them to prove that the medical theory linking the Hepatitis B vaccine with edema and an adverse reaction known as "cytokine storm" was "more likely than not," instead of establishing that the theory was medically plausible. Finally, the Court found that the Special Master had not considered the totality of the evidence in finding that Monica's brain weight of 570 grams was within the normal range. The Court found that the Special Master did not address Petitioner's evidence of normal brain weight and appeared to rely on a study whose subjects suffered moderate to severe edema as a marker of normal brain weight. The Court instructed the Special Master to reevaluate the totality of evidence on brain weight and reconsider her conclusion that Monica's brain weight was within the normal range.

The Special Master's Decision On Remand

In her Decision on Remand, the Special Master again determined that Petitioners were not entitled to compensation under the Vaccine Act, applying the Althen test and finding that Petitioners had not established a prima facie case. On remand, the Special Master concluded that Petitioners had satisfied their burden under Althen's first prong, in that they proffered a biologically plausible medical theory causally connecting the vaccination and the injury. However, the Special Master found that Petitioners failed to satisfy their burden of proof as to Althen's second and third prongs.

With respect to Althen prong two -- "logical sequence of cause and effect showing that the vaccination was the reason for the injury" -- the Special Master concluded that "in the absence of other evidence that would support a finding that Child Doe/11 suffered an encephalopathic injury," she was not persuaded that Monica's somnolence represented the "significantly decreased level of consciousness" indicative of encephalopathy. Doe III, 2008 WL 4899356 at *9-13. The Special Master noted that Monica's medical records contained no references to any other standard symptoms of

encephalopathy, such as "irritability, fever, vomiting, or seizures." Id. at * 13.

In assessing whether Monica's brain weight at autopsy was significantly heavy and edematous, the Special Master considered all the record evidence on brain weight. The Special Master credited the expert opinion of pediatric neuropathologist Dr. Enid Gilbert-Barness that Monica's brain was not significantly heavy or edematous and concluded that Monica's body length and body weight, which were in the 95th and 90th percentile respectively, were not out of proportion with Monica's brain weight "and not much beyond, if at all beyond, the range of normal brain weight." Id. at * 17.

In the context of assessing Petitioners' evidence under Althen's prong-two causation, the Special Master also considered the competing experts' views on whether Monica's death was a SIDS death. The Special Master credited the testimony of Respondent's expert, Dr. Gilbert-Barness, that most deaths attributable to SIDS actually resulted from asphyxiation and that Monica's nap environment placed her at risk of accidental asphyxiation. The Special Master also cited

studies that correlate SIDS diagnoses with a heavy brain at autopsy. The Special Master clarified that she considered evidence regarding potential alternative causation for the limited purpose of evaluating Petitioners' "proposed causal sequence for a vaccine injury." Id. at *22.

In continuing to assess prong two, the Special Master weighed the competing expert testimony on whether Monica's Hepatitis B vaccination had triggered a cytokine storm. The Special Master credited the testimony of Respondent's expert, pediatric immunologist Dr. Christine McCusker, who concluded that a cytokine storm and life-threatening inflammation in Monica's brain would not have resulted from a vaccination administered in her thigh because such a cytokine reaction would occur locally, not over long distances, and because cytokine-induced cerebral edema has only been shown where brain tissue is infected or compromised by viruses. Dr. McCusker also found a disconnect in the causal chain between vaccination and death because Monica did not exhibit the symptoms of a cytokine reaction -- headache, restlessness, vomiting, nausea, diarrhea, rapid heartbeat, drop in blood pressure, respiratory failure or renal impairment. The Special Master

concluded that Petitioners' proposed sequence of events leading from vaccine to encephalopathy did not "appear to be supported by the facts of the case," based primarily on her determination that the evidence, in particular the testimony of Petitioners' pathology expert Dr. John J. Shane, did not establish that Monica's brain was significantly heavy or edematous, which left an "absence of clinical symptoms of the type and severity that would be expected . . . ." Id.

Examining Althen's prong three, the Special Master determined that Petitioners failed to establish a temporal relationship between Monica's vaccination and her injury. The Special Master credited Dr. McCusker's testimony that Monica's death occurred too soon to have resulted from a cytokine storm in lieu of the contrary testimony of Petitioners' immunology expert, Dr. Alan S. Levin. In weighing the testimony and credibility of Petitioners' expert, the Special Master observed that Dr. Levin first testified that a cytokine storm could develop in seven hours, incorrectly believing that Monica's death occurred "eight hours or something like that" after vaccination. Id. at *28-29; see Tr. at 308, 310-11. He lowered his assessment ("[t]hree hours is also reasonable")

when counsel and the Special Master pointed out that Monica had died within three to four and one-half hours after vaccination. Tr. at 311-12. Dr. Levin also distinguished the study cited by Dr. McCusker -Respondent's Exhibit DD -- because it involved healthy adults, one of whom "passed out" only 2.5 hours after injection. Id.[FN7] However, the Special Master viewed this study differently, noting that all of the study's subjects suffered symptoms during the first two to three hours after injection that Monica did not exhibit. The Special Master concluded that the record did "not support the compressed time frame that Dr. Levin proposed . . . [or] a finding in petitioners' favor regarding the causal relationship between Child Doe/1 1 's vaccination and her death." Doe III, 2008 WL 4899356 at *29-30.

Discussion

Jurisdiction And Standard Of Review

Jurisdiction lies in this Court pursuant to 42 U.S.C. § 300aa-12(e). In reviewing a decision of the Special Master, this Court may (1) uphold the fmdings of fact and conclusions of law, (2) set aside any of the Special Master's findings of fact or

conclusions of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or (3) "remand the petition to the Special Master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2)(A)-(C); Althen, 418 F.3d at 1277-78; Saunders v. Sec'y of HHS, 25 F.3d 1031, 1033 (Fed. Cir. 1994). Findings of fact of the Special Master are reviewed under the arbitrary and capricious standard, legal questions are reviewed under the "not-in-accordance-with-law" standard, and discretionary rulings are reviewed under the abuse of discretion standard. Saunders, 25 F.3d at 1033 (quoting Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

This Court must uphold the Special Master's findings unless it concludes that those findings are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. See 42 U.S.C. § 300aa-12(e)(2)(B). Reversible error is "extremely difficult to demonstrate" if the Special Master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." Hines v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991). As the Federal Circuit recognized, it is not the role of a

court reviewing a special master's decision to reweigh the factual evidence or to assess whether a special master correctly evaluated the evidence. Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (citing Munn, 970 F.2d at 871).

A decision is arbitrary and capricious if it relied on factors that Congress has not intended, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence, or is so implausible that it could not be ascribed to a difference in view or the product of the Special Master's expertise. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); Hines, 940 F.2d at 1527-28.

Elements And Burden Of Proof

The Vaccine Act provides two methods for a petitioner to establish causation. See 42 U.S.C. § 300aa-13(a)(1); Walther v. Sec'y of HHS, 485 F.3d 1146, 1149 (Fed. Cir. 2007); Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006); Althen, 418 F.3d at 1278. First, causation of an injury due to a vaccination is presumed if a petitioner demonstrates, through medical records

or expert testimony, that the injury is one listed in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), and shows by a preponderance of the evidence that the injury occurred within the time provided by the Table. Capizzano, 440 F.3d at 1319-20; Munn, 970 F.2d at 865.

Second, in a case such as the instant action where the alleged injury is not listed in the Vaccine Injury Table, a petitioner must establish causation-in-fact. Walther, 485 F.3d at 1149; Pafford v. Sec'y of MIS 451 F.3d 1352, 1355 (Fed. Cir. 2006); Shyface v. Sec'y of HHS, 165 F.3d 1344, 1350-51 (Fed. Cir. 1999). The Act provides:

> Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—
>
> (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section [300aa-11(c)(1)], and
>
> (B) that there is not a preponderance

> of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.
>
> The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

42 U.S.C. § 300aa-13(a)(1).

A petitioner can establish a prima facie case on causation by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.'" De Bazan v. Sec'y of HHS, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008), (quoting Althen, 418 F.3d at 1278); see also Walther, 485 F.3d at 1150; Capizzano, 440 F.3d at 1324. A petitioner must show that the vaccine was a "substantial factor" in bringing about the

harm, not merely a "non-negligible" factor. De Bazan, 539 F.3d at 1351 (citing Shyface, 165 F.3d at 1352 and the Restatement (Second) of Torts § 432(1)).

If the petitioner establishes a prima facie case, the burden of proof shifts to the respondent to prove by a preponderance of the evidence that the "illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. § 300aa-13(a)(1)(B); Walther, 485 F.3d at 1151.

The Act defines a "factor unrelated" as follows:

> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
>
> (B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known

> relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

42 U.S.C. 300aa-13(a)(2).

The separate "factor unrelated" inquiry is to be made only after the Special Master has determined that a petitioner has successfully put forward a prima facie case of causation. Walther, 485 F.3d at 1151-52; Grant v. Sec 'y of HHS, 956 F.2d 1144, 1149 (Fed. Cir. 1992). If the Government fails to rebut the petitioner's prima facie showing of causation by a preponderance of evidence, the petitioner is entitled to compensation under the Act. De Bazan, 539 F.3d at 1352; Walther, 485 F.3d at 1151; 42 U.S.C. § 300aa-13(a)(1)(B).

If the record evidence is in equipoise on any requisite element of proof, the party bearing the burden of proof with respect to such element cannot prevail because that party has not marshaled a preponderance of the evidence in its favor. See

Knudsen v. Sec'y of HHS, 35 F.3d 543, 550 (Fed. Cir. 1994) (recognizing with regard to alternative causation that "[i]f the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded").

The Special Master Properly Applied The Althen Factors In Her Decision On Remand

Petitioners argue in their Motion for Review that the Special Master committed several legal errors in her decision following remand. First, although Petitioners applaud the Special Master's conclusion under Althen's prong one that the Hepatitis B vaccine can cause cytokine storm, edema, and death, they fault her failure to articulate a sufficient rationale for this conclusion. Because this is the first case in which the Hepatitis B vaccine has been found capable of causing this reaction, Petitioners contend that the Special Master was required to explain her reasoning to impart sufficient precedential value to the decision. They further argue that the Special Master's failure to do so prejudiced them in building their case and urge this Court to step in and articulate a rationale in support of this admittedly proper legal conclusion.

The Court declines, as such action is unwarranted under the circumstances here.

In its earlier decision, this Court concluded that the Special Master had erred in her prong-one analysis by requiring Petitioners to demonstrate that their medical theory of causation be "more likely than not" and instructed the Special Master to apply a different legal standard on remand, i.e., whether Petitioners' theory of causation was biologically plausible. Doe II, 83 Fed. Cl. at 173-74. This Court quoted Althen's statement that a "possible link" between a vaccination and injury may permit a finding of causation even though the link involved a "sequence hitherto unproven in medicine." See id. at 174 (quoting Althen, 418 F.3d at 1280).[FN8] The Special Master followed this instruction, concluding that Petitioners had satisfied prong one based upon the testimony of Petitioners' experts Dr. Levin and Dr. Shane, and the literature they cited.

Nor have Petitioners demonstrated that the Special Master's failure to set forth an expansive rationale for this conclusion prejudiced their case. In attacking the Special Master's prong-two analysis, Petitioners contend that the Special

Master erred by conflating her Althen prong-one and prong-two analyses. The Special Master did not conflate these analyses in her remand decision, but properly separated prong one from prong two. Legal error cannot be demonstrated simply because the Special Master concluded that Petitioners satisfied Althen prong one but failed to prove prong two. As the Federal Circuit articulated in Capizzano:

> The second prong of the *Althen III* test is not without meaning. There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused

the injury by preponderant evidence.

440 F.3d at 1327 (emphasis in original).

Petitioners argue that the Special Master, after conceding Petitioners had satisfied their burden under Althen's "can cause" prong, "appears to denigrate her own . . . finding that Hepatitis B vaccine can cause cytokine storm" by ultimately favoring Dr. McCusker's testimony denying Althen's "did cause" prong. Pet'rs' Mot. for Review at 18. While Dr. McCusker did espouse generalized principles disputing the medical plausibility of a cytokine storm resulting from a Hepatitis B vaccination, Dr. McCusker articulated specific reasons demonstrating why she concluded Monica did not experience a cytokine storm -- the vaccine was given too far away from the locus of the cytokine storm (in the thigh) and none of the symptoms associated with cytokine storm in a study -- headache, fever, vomiting, bowel distress and hypotension -- appeared in Monica. In short, Petitioners have not demonstrated error in the legal framework of the Special Master's prong-one and prong-two analyses.

The Special Master's Fact-Finding On Brain Weight Was Not Arbitrary And Capricious

Petitioners next argue that Monica's brain weight is the determinative factor for assessing whether the Hepatitis B vaccine caused Monica's death and take issue with the Special Master's fact- finding on brain weight. Petitioners allege two errors in the Special Master's fact-finding on brain weight -- her reliance on the same skewed study the Court cautioned against when it remanded the case, and her determination that Monica's height was 23 inches -- a measurement not in the record -which informed the Special Master's analysis of brain weight. Id. at 35-36.[FN9]

Before turning to these specific allegations of error, the Court notes that Petitioners' contention that brain weight is the dispositive indicator of causation is flawed. Petitioners posit that Monica's significantly heavy brain weight demonstrates a high degree of edema which demonstrates that a cytokine storm, triggered by the Hepatitis B vaccine, erupted. Two considerations refute this argument. First, as the Special Master recognized, the evidence of edema is not confined to brain weight alone. Rather, there is other evidence apart from evidence of brain weight

that establishes that Monica's brain was not significantly edematous. The autopsy report found no edema except in the lungs, and expressly noted that the condition of Monica's brain was "grossly unremarkable" with "no evidence of edema or herniation." Pet'rs' Ex. 6 at 5. The Vaccine Act directs special masters to consider the "relevant medical and scientific evidence contained in the record," including the "autopsy or coroner's report" in determining whether to award compensation. 42 U.S.C. § 300aa13(b)(1). The autopsy slides do not establish severe edema either -- the evidence of what the slides show is in equipoise. While Petitioner's expert, Dr. Shane, claimed to have seen halo formation, or clear spaces around the glial cells and the blood vessels of the brain, in the autopsy slides that he attributed to cerebral edema, Respondent's expert, Dr. Gilbert-Barness, who examined the same slides, did not observe such phenomena; she did "not see the changes that Dr. Shane described." Compare Pet'rs' Ex. 11 at 1-2, and Tr. at 61, with Tr. at 122.

Second, there is a further problem with Petitioners' evidence on causation independent of the issue of brain weight -- the lack of evidence that a cytokine storm occurred. Dr. McCusker, an expert in pediatric immunology, disagreed with Petitioners' contention

that Monica died as the result of a "cytokine storm" caused by the Hepatitis B vaccination. Tr. at 243. While Dr. McCusker agreed with Petitioners' expert, Dr. Levin, that a vaccination induces a cytokine response from the immune system to counter the antigens released by the vaccination, she noted that only in rare cases does a cytokine storm occur. Id. at 251-53. Further, Dr. McCusker testified that a cytokine storm begins with symptoms that Monica did not display -- headache, fever, vomiting, bowel distress, and hypotension. In addition, Dr. McCusker testified that while a cytokine storm frequently results in vascular collapse and multi-organ failure, Monica's autopsy results showed no signs of inflammation consistent with multi-organ failure. Tr. at 254-55, 260-61; Resp't's Ex. E. Dr. McCusker further testified that the inflammatory effects of a cytokine reaction are primarily local, and because Monica received her Hepatitis B vaccination in the leg, "there's no way to connect that with a life-threatening encephalitis or encephalopathy." Tr. at 249, 257-58, 291. Thus, according to Respondent's expert, Monica did not exhibit the expected symptoms of a cytokine storm.

Importantly, the Special Master's conclusion that Petitioners had not proven that Monica's brain

was severely edematous or that a cytokine storm had occurred was dependent upon her assessment of the credibility of conflicting experts -- determinations that are "virtually unreviewable" on appeal. Bradley v. Sec'y of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993). For example, while Dr. Shane observed "halos" indicative of edema in Monica's brain, Dr. GilbertBarness testified that she did "not see the changes that Dr. Shane described." Compare Pet'rs' Ex. 11 at 1-2, with Tr. at 122. While Petitioners' experts testified that Monica's heavy organs were consistent with their cytokine storm theory, Respondent's experts attributed this heaviness to blood congestion. Tr. at 142, 144-46. In short, the expert testimony that the Special Master credited militated against a finding of severe edema resulting from a cytokine storm.

Nor can this Court conclude that the Special Master's findings on brain weight were arbitrary and capricious. On remand the Special Master followed this Court's instructions and assessed all of the evidence on brain weight. In attacking the Special Master's fact-finding on brain weight, Petitioners argue that the Special Master continued to rely on the skewed study "Brain Weight of Danish Children," Respondent's Exhibit LL.[FN10] While

Petitioners are correct that this study should not have been used in establishing a baseline for normal brain weight since 83% of the subjects had edematous brains, this error -- mention of the flawed study -- does not undermine the Special Master's conclusion that Petitioners failed to prove that Monica's brain was significantly heavy and edematous. It is Petitioners who have the burden of proving that Monica's brain weight of 570 was significantly heavy and edematous as a result of a cytokine storm triggered by the vaccine[FN11] Even removing this study from the analysis, the remaining evidence of record does not, as Petitioners posit, establish that Monica's brain weight was significantly heavy and edematous.

The Special Master did not depend exclusively on Exhibit LL for her conclusion that Monica's brain at autopsy "reflected a marginally increased brain weight beyond the heaviest listed brain weights . . . within the normal range for her age group." Doe III, 2008 WL 4899356 at *15. Petitioners' own expert considered a brain weight of 555 grams (accounting for error) on the high side of normal, and Petitioners' experts did not explain why Monica's brain weight of 570 grams was "significantly" heavy in light of the fact that 555 grams represented the top of the purported normal range. Tr. at 68-69, 105-06. All of the

experts agreed that Monica's brain was heavy; what was disputed was whether it was "significantly" heavy or so heavy as to be severely edematous resulting from a cytokine storm.[FN12]

Second, Petitioners claim that the Special Master improperly calculated Monica's body length at 23 inches, a measurement not in the record, and used that measurement to inform her assessment of brain weight. The record regarding Monica's length is contradictory. While Dr. Shane relied on Monica's growth chart to conclude that she was in the 50th percentile for height, other records indicated that Monica was in the 95th percentile for height. Compare Pet'rs' Ex. 3 at 7, with Pet'rs' Ex. 2 at 2, 3. The Special Master's decision to credit hospital records from the day of Monica's birth that indicate she was in the 95th percentile for height was not arbitrary and capricious. Doe III, 2008 WL 4899356 at *16; Pet'rs' Ex. 2 at 2, 3. The Court also finds reasonable the Special Master's reliance upon "the length at autopsy [as] the proper measurement" because of the absence of "the difficulties associated with measuring the length of a squirming baby." Doe III 2008 WL 4899356 at * 16 n.29. Monica's autopsy report stated that she measured 25 inches in height at death -- which would place Monica well above the

95th percentile in height according to Monica's pediatric growth chart. Pet'rs' Ex. 3 at 7. Petitioners argue that the 25-inch measurement is "clearly wrong" because it would have required Monica's pediatrician "to be wrong by 3 and 1/4 inches," and would have required her to grow at the rate of "3/4 of an inch a week" from birth. Pet'rs' Mot. for Review at 35. The Special Master extrapolated a shorter length from other evidence in the record, and there is no basis to overturn the Special Master's decision to credit one set of height measurements over another.[FN13] Given the contradictions in the record, the Special Master did not err in extrapolating that Monica's height approximated 23 inches and using that measurement to inform her decision that Monica's height was consistent with a heavy brain weight. There is evidence indicating that Monica was a long baby -- medical records indicating she was in the 95th percentile at birth and above the 95th percentile at autopsy.

Given the totality of the evidence on brain weight, Petitioners have not established that the Special Master's conclusion that Monica's brain weight was not significantly heavy, or edematous was arbitrary and capricious. The Special Master's reference to the flawed study and extrapolation of

Monica's body length were at most harmless error as they were not critical to this result. Even removing consideration of the skewed study and the Special Master's extrapolation of Monica's length, substantial evidence supports the Special Master's conclusion that Petitioners failed to prove a prima facie case on prong two. See, e.g., Hines v. Sec'y of HHS, 940 F.2d 1518, 1526 (Fed. Cir. 1991) ("[E]ven if it was error, it was harmless because . . . the special master's decision was based on a number of factors and she has not shown that reliance on the judicially noticed incubation period . . . was likely critical to the result.").

The Special Master Properly Considered Evidence of Alternative Causation in Assessing Petitioners' Prima Facie Case

Petitioners also argue that the Special Master ignored the Court's remand instructions by including within her prong-two analysis a discussion of SIDS, a potential "factor unrelated." Pet'rs' Mot. for Review at 18-20. Because the Special Master determined on remand that Petitioners did not establish a prima facie case, it was unnecessary for her to shift the burden of proof and reach the issue of whether respondent demonstrated that a factor unrelated

caused Monica's death. Nevertheless, the Special Master did assess the conflicting expert testimony on SIDS in her decision on remand. See Doe 111, 2008 WL 4899356 at *19-22. Petitioners argue that the Special Master's intermingling of the SIDS discussion in the prong-two analysis constituted legal error. The Court disagrees.

The Special Master cited testimony from Dr. Shane and Dr. Gilbert-Barness, who agreed that SIDS, a term once used to describe unexplainable infant deaths, has 'become a definable disease process.'" Id. at * 19 (quoting testimony of Dr. Shane, Tr. at 77-78). Dr. Shane stated that SIDS deaths often are connected with upper respiratory problems. Id. Dr. Gilbert-Barness testified that most deaths attributed to SIDS actually resulted from asphyxiation caused by "'the [sleeping] position . . . and . . . the hazards of mattresses, beds and bedding.'" Id. at *20 (quoting Tr. at 123 (alteration in original)). Dr. Gilbert-Barness testified that "'examination of the death scene' is one of the most important steps in clarifying a SIDS diagnosis, and that Monica's nap environment put her at risk of accidental asphyxiation. Id. (citing Tr. at 123-24, 126). The Special Master credited testimony from Dr. Gilbert-Barness describing "overlaying" and "wedging" as

methods of accidental asphyxiation and cited studies submitted by Respondent that correlate SIDS diagnoses with heavy brain weights at autopsy. Id. at *21, *22 n.32; see Resp't's Ex. MM at 1 (study reporting that 57 percent of brains from SIDS victims were above the 99th percentile in brain weight); Resp't's Ex. KK at 9 (study reporting that 81 percent of SIDS victims were above the 95th percentile in brain weight).

In the context of assessing Althen's prong two, the Special Master determined that:

> Many of the classic findings in a post mortem examination of a SIDS case were present in Child Doe/11 at autopsy. She was a long, weighty baby with a large brain. Although there was evidence of some edema in her brain, because edema of the degree that Dr. Shane asserted was present in Child Doe/11 is accompanied generally by clinical symptoms of a severity and type that were not present in this case, . . . the undersigned is not persuaded that the edema was as severe as Dr.

Shane described.

2008 WL 4899356 at *21.

The Special Master, however, did not go so far as to conclude that the cause of Monica's death was SIDS. Rather, the Special Master simply considered the evidence that "many of the classic findings" of a SIDS death were present in Monica in the course of assessing whether Petitioners had met their burden of proving their prima facie case that the Hepatis B vaccine caused Monica's death. The Special Master explained:

> The undersigned considered, as a whole, the testimony of petitioners and of the parties' experts regarding Child Doe/11 's clinical and pathological presentation (including the experts' discussion about the expected pathological findings in an explained SIDS death), the filed medical literature and the medical records in evaluating whether petitioners' medical theory reflected a logical sequence of cause and effect supported by a reliable medical explanation. The testimony of

respondent's experts and the literature filed by respondent's experts exposed the difficulties with petitioners' proposed theory. . . . Although some of the testimony and literature supplied by respondent might also have advanced a claim of alternate causation by respondent if petitioners had prevailed in proving a prima facie case, the undersigned considered the aspects of the offered evidence (including that offered by respondent) for the limited purpose of evaluating carefully the reliability of the medical underpinnngs of petitioners' proposed causal sequence for a vaccine injury.

Here, petitioners' proposed sequence of post-vaccinal events that led to an encephalopathy does not appear to be supported by the facts of the case. Dr. Shane's opinion of causation rested heavily on his view that Child Doe/1 1 's brain was heavy and that heaviness necessarily indicated that Child Doe/1 1 had moderate to moderately severe

> edema, . . . and the opinion of petitioners' expert, Dr. Levin, rested as well on a finding of significant edema in Child Doe/1 1 's brain based on Dr. Shane's opinion of Child Doe/1 1 's pathology . . .. In the absence of clinical symptoms of the type and severity that would be expected medically in circumstances in which the pathological picture was as dire as petitioners' experts described, however, the undersigned is not persuaded that Child Doe/11's pathological presentation was, in fact, as critical as petitioner's experts have asserted. Because the undersigned finds that petitioners have not carried their burden of proving that Child Doe/1 1 's brain was significantly edematous, an important aspect of petitioners' proposed sequence of cause and effect, petitioners do not prevail on the second prong of the Althen standard.

Id. at *22. The Special Master did not require Petitioners to eliminate SIDS as an alternative cause. Rather, the Special Master simply weighed the SIDS evidence as part of the totality of the

evidence in considering Althen's prong two. The Special Master weighed the evidence of Monica's brain weight and edema and compared it with similar indicators of SIDS deaths to assess whether the severity of Monica's edema and the heaviness of her brain comported with Petitioners' claim that the Hepatitis B vaccine had induced a cytokine storm, edema and death. Petitioners have not demonstrated that the Special Master's review of the SIDS evidence for this limited purpose was error.

The Special Master's consideration of SIDS is consistent with the Federal Circuit's recent guidance in De Bazan v. Secretary of Health and Human Services, 539 F.3d 1347, 1353 (Fed. Cir. 2008), which was issued after this Court's decision remanding this case. There, the Federal Circuit held that a special master may consider proof relating to alternative causes in assessing whether the petitioner established a prima facie case. The Federal Circuit explained that the respondent "is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief" De Bazan, 539 F.3d at 1353. The Federal Circuit clarified:

> While a failure of proof that the vaccine was the cause of the petitioner's injury suggests that some other cause was responsible, that is not equivalent to having proven by preponderant evidence that a *particular* agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor).

Id. at 1354 (emphasis in original). Here, consistent with De Bazan, the Special Master properly considered the record as a whole in evaluating Petitioners' prima facie case -- including respondent's expert's characterization of overlaying or wedging as a method of accidental asphyxia or SIDS and a potential alternative cause of Monica's death.

The Federal Circuit in Pafford, 451 F.3d at 1359 also approved the special master's consideration of potential alternative causes in assessing whether a petitioner had proven a prima facie case of causation in fact. The Pafford court

stated:

> Without a link between Still's disease and the vaccinations, the Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations. . . . Hence, petitioner did not show it was *more* likely that the vaccinations were a but-for cause of and a substantial factor in her contracting Still's disease.

Id.; cf. Walther, 485 F.3d at 1151 (stating that "a petitioner is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a prima facie case, as was true in Pafford").

By considering the record in its entirety, the Special Master followed the directive of the Vaccine Act, which states that "[c]ompensation shall be awarded . . . if the special master or court finds on the record as a whole . . . that the petitioner has

demonstrated by a preponderance of the evidence" the claims of the petition. 42 U.S.C. § 300aa-13(a)(1) (emphasis added). Moreover, because the autopsy report listed SIDS as the cause of Monica's death, and both Petitioners and Respondent introduced evidence on SIDS as a potential cause of Monica's death, it was proper for the Special Master to consider evidence relating to SIDS as a potential alternative cause in assessing Petitioners' prima facie case. The Vaccine Act directs special masters to consider the "relevant medical and scientific evidence contained in the record," including the "autopsy or coroner's report" in determining whether to award compensation. 42 U.S.C. § 300aa-13(b)(1).

The Special Master Correctly Determined That Petitioners Failed to Prove Temporal Proximity Under Althen's Prong Three

Petitioners must establish each prong of the Althen test independently in order to make out a prima facie case of causation. Failure to satisfy any of the three prongs prevents Petitioners from making their prima facie showing. Thus, even if Petitioners had demonstrated that the Special Master wrongly assessed the evidence of brain

weight, cytokine storm and edema, and that they had in fact satisfied Althen's prong two, they still must establish a proximate temporal relationship between the vaccination and injury under prong three in order to prevail. Petitioners' Motion for Review does not point to any discrete reversible error in the Special Master's prong-three analysis. Instead, Petitioners state that the Special Master's decision:

> makes it clear that she views the pathology in this case as integral to answering the question posed by *Althen* step 3. This actually makes some sense. If Hepatitis B vaccine can cause wide spread edema, and cerebral edema, because it is a superantigen, and Monica had the pathological findings the petitioners claim . . . then one would logically look for an exposure to a superantigen. Hepatitis B is the only superantigen we have to choose from in this case. Therefore, the answer to *Althen* step 3 is intertwined with the answer to *Althen* step 2.

Pet'rs' Mot. for Review at 27.

Contrary to Petitioners' characterization, the Special Master did not make it clear that she viewed "the pathology in this case as integral to answering the question posed by *Althen* step 3." Id. Instead, she relied upon Dr. McCusker's testimony that Monica did not exhibit the symptoms of a cytokine storm, symptoms which should have appeared within 50-90 minutes of the injection.

Further, while Petitioners endeavor to characterize the Special Master's decision as intertwining the analysis of Althen steps two and three, making her conclusion on step three wholly dependent upon her conclusion on step two, the Special Master properly segregated the proof on each step. As required by precedent, the Special Master separately considered Althen prongs two and three. See Pafford, 451 F.3d at 1360 ("[T]he Special Master did not err in requiring specific evidence about a medically acceptable time frame linking the [injury] to the vaccinations at issue."). In her prong three analysis, the Special Master determined that Petitioners failed to establish a proximate temporal relationship between

vaccination and injury because Monica's death occurred some four hours after her vaccination. In so ruling, the Special Master credited the testimony of Dr. McCusker that Monica's death occurred "too soon" to have resulted from the Hepatitis B vaccine. Tr. at 258. Dr. McCusker testified: "[T]he progression occurs over days. It doesn't happen over hours. It takes days for there to accumulate enough edema . . . for the final event to occur." Id. at 258. Dr. McCusker cited a study, Respondent's Exhibit DD, that demonstrated the effects of a cytokine storm on a group of healthy adults, all of whom suffered early symptoms, such as restlessness, nausea, vomiting and diarrhea, that Monica did not display. Id. at 252-55, 259-61; Doe 2008 WL 4899356 at *29. This study's subjects all began to show symptoms of an excessive cytokine reaction within the first 50 to 90 minutes after their injections; however, Monica did not show any such symptoms during that time. Resp't's Ex. DD at 2; Doe III, 2008 WL 4899356 at *30.[FN14]

Petitioners have not articulated any basis for overturning the Special Master's decision to credit the testimony of Dr. McCusker. So too, the Special Master reasonably discounted the testimony of Dr. Levin. This expert first opined

that a cytokine storm could develop in seven hours, but then, after being reminded that Monica's father discovered that Monica was blue in the face and not breathing four to four and one-half hours after the vaccination, instead opined that a cytokine storm could develop in just three hours. Tr. at 308, 310-12. This Court sees no reason to disturb the Special Master's credibility determination. As the Federal Circuit has recognized, the Special Master's determinations about the credibility of expert witnesses are "'virtually unreviewable'" on appeal. Bradley, 991 F.2d at 1575 (quoting Hambsch v. Dept. of the Treasury, 796 F.2d 430, 436 (Fed. Cir. 1986)); Munn, 970 F.2d at 871 (stating that a reviewing Court should not "examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder."); see also Nordwall v. Sec 'y of HHS, 83 Fed. Cl. 477, 491 (stating when referring to expert testimony that "[i]t is not the job of the Court to second guess the Special Master's credibility determination").

Moreover, no other persuasive evidence supports the conclusion that a cytokine storm developed in Monica in the abbreviated time frame of three to four hours. Rather, other evidence on

temporal proximity suggests that Monica's death did not result from a cytokine storm in such a short timeframe. In addition, no persuasive evidence directly addressed how a child of Monica's age could die from a cytokine storm before exhibiting any of the documented symptoms of such a reaction.

In sum, there is no basis to disturb the Special Master's reasonable conclusion under Althen's prong three that Monica's death occurred too soon to have been caused by the vaccine. See De Bazan, 539 F.3d at 1352 (stating "we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked").

Conclusion

1. This Court upholds the fmdings of fact and conclusions of law of the Special Master.

2. The Petition for Review is DENIED.

3. The Clerk shall not disclose this de cision publicly for 14 days.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Judge

FN1 In accordance with the Rule 18(b) of the Rules of the United States Court of Federal Claims (RCFC), Appendix B, this opinion is filed under seal. Each party is afforded 14 days from the date of sealed filing to object to the public disclosure of any information supplied by that party.

FN2 The background is set forth in the Special Master's decisions and this Court's earlier decision and will be briefly summarized here. See Doe/11 v. Sec'y of HHS (Doe I), No. 99-212V, 2008 WL 649065 (Fed. Cl. Spec. Mstr. Jan. 31, 2008); Doe/11 v. Sec'y of HHS (Doe II), 83 Fed. Cl. 157 (2008); Doe/11 v Sec'y of HHS (Doe BI), No. 99-212V, 2008 WL 4899356 (Fed. Cl. Spec. Mstr. Oct. 29, 2008).

FN3 The Hepatitis B vaccine is "a noninfectious viral vaccine derived by recombination from Hepatitis B surface antigen and cloned in yeast cells [and] administered intramuscularly for immunization of children and adolescents and of persons at increased

risk for infection." Dorland's Illustrated Medical Dictionary 2044 (31st ed. 2007).

FN4 Dr. Anthony did not testify at the hearing, and his credentials are not in the record.

FN5 As the Special Master noted, edema is 'the presence of large amounts of fluid in the intercellular tissue spaces of the body, usually referring to demonstrable amounts in the subcutaneous tissues.' Doe III, 2008 WL 4899356 at *5 n.15 (quoting Dorland's Illustrated Medical Dictionary 589 (30th ed. 2003)).

FN6. The Special Master described SIDS as follows:

SIDS is "the sudden and unexpected death of an apparently healthy infant, typically occurring between the ages of three weeks and five months, and not explained by careful postmortem studies." *Dorland's Illustrated Medical Dictionary* 1833 (30th ed. 2003). Additionally, "sudden infant death syndrome" has been defined by a panel convened by the National Institute of Child Health and Human Development as "the sudden death of an infant under 1 year of age which remains unexplained after

a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history." Ps' Ex. 20 at 2 (Ramzi S. Cotran, et al., *Robbins Pathologic Basis of Disease* (6th ed.1997) . . . . The death usually occurs while the infant is asleep. *Id.* As a diagnosis of exclusion, SIDS is the rendered diagnosis when neither the autopsy, the examined death scene nor the clinical history yields an explanation for the death. *See id.; see also* R's Ex. FF (Marie Valdes-Dapena, M.D., *Sudden Infant Death Syndrome: Pathologic Findings,* Vol. 19, No. 4 Clinics in Perinatology, at 703 (Dec.1992).

Doe III, 2008 WL 4899356 at *5 n.12 (emphasis in original omitted).

FN7 This study, Ganesh Suntharalingam et al., Cytokine Storm in Phase 1 Trial of the AntiCD28 Monoclonal Antibody TGN1412, 355 New Eng. J. Med. 1018, 1018-28 (2006), described a cytokine storm induced in otherwise healthy trial subjects by the intravenous injection of an experimental drug.

FN8 Accord Nussman v. Sec'y of HHS, 83 Fed. Cl. 111, 118 (Fed. Cl. 2008) (stating a petitioner is not

required to prove the proffered medical theory, citing the special master's decision in that case which cited Knudsen, 35 F.3d at 549).

FN9 Petitioners also argue that the Special Master should have regarded Monica's somnolence as a symptom of encephalopathy. Pet'rs' Mot. for Review at 20-22. However, Petitioners' expert, Dr. Shane, stated that he would defer to a pediatrician on whether somnolence was a normal reaction to a vaccination. Tr. at 87. Respondent's experts, both of whom are pediatricians, testified that Monica's somnolence was a normal reaction to the vaccine. Tr. at 139, 251, 288-89. It was therefore reasonable for the Special Master to discount Monica's somnolence as a symptom of encephalopathy.

N10 The Special Master had accepted Dr.Gilbert-Barness' two estimates of normal brain weight -- 516 grams and 560 grams -- without considering the totality of the evidence. In addition, the brain weight chart from which Dr. Gilbert-Barness drew her high-end estimate of 560 grams for a normal brain weight was taken from a study in which 83% of the subjects suffered from moderate to severe edema -- a fact that the authors of that study recognized contributed to a

"systematically higher" mean weight. Resp't's Ex. LL at 11.

FN11 The Special Master observed that Monica's brain weight was within the normal range in the context of assessing whether Petitioners had met their burden of establishing that Monica's brain was both significantly heavy and edematous.

FN12 According to the 490-gram mean and 51-gram standard deviation relied on by Petitioners' expert, Dr. Shane, Monica's brain at autopsy was 570 grams -- 80 grams heavier than Petitioners' proffered mean of 490 grams. Her brain weight was within approximately 1.57 standard deviations of Petitioners' mean. Petitioners did not address whether this deviation was significant in this context as requested by the Court. See Tr. at 23 and Order dated January 16, 2009.

FN13 Petitioners question how the Special Master arrived at her estimate that Monica was nearly 23 inches in height at death. Pet'rs' Mot. for Review at 35. It appears that the Special Master extrapolated this number by taking the height of 21.75 inches listed in Monica's hospital records and increasing it by the "growth differential" listed in Monica's growth charts

over a period of seven weeks. See Doe III, 2008 WL 4899356 at *16.

FN14 The one symptom Petitioners identified in Monica -- somnolence -- does not establish a cytokine storm. Dr. McCusker testified that Monica's somnolence was a normal reaction to a vaccination. Tr. at 288-89.